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10/588,192

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Romed Meirer

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HUNTON & WILLIAMS LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
2200 Pennsylvania Avenue, N.W.  
WASHINGTON, DC 20037

EXAMINER

SANTOS, JOSEPH M

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

01/18/2012

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/588,192 | <b>Applicant(s)</b><br>MEIRER ET AL. |  |
|                              | <b>Examiner</b><br>JOSEPH M. SANTOS  | <b>Art Unit</b><br>3737              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 November 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 34-56 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 34-56 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

***DETAILED ACTION***

***Claim Objections***

1. Claims **35, 37, 44** are objected to because of the following informalities: In claim 35, the term "with" should be deleted.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims **34-37, 39-48, 50-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over George et al (US 6,334,069) in view of Ogden et al. (US 6,390,995) in view of Sanctis et al. "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia".

George et al discloses a method and apparatus for the treatment of chronic wounds on a patient's skin using pulsed electromagnetic (EM) energy. Such treatment provides healing treatment to burns and surgically implanted skin graft

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(see abstract, col. 10, lines 18-26). However, George et al fails to specifically teach to treat the skin using shock waves pulses provided by a shock wave applicator having the claimed number of pulses and energy flux density. In the same field of endeavor, Ogden et al. disclose a therapeutic device and method used to generate acoustic shock waves medical treatment of a variety of pathological conditions associated with bone environments and musculoskeletal environments; such shock waves induce soft tissue morphogens and growth factors (see col. 3, lines 17-44). Ogden et al further teach the number shock wave pulses per treatment should be approximately 500-10,000 (see, col.6, lines 5-8). It would have been obvious to one skilled in the art to replace one type of wave (EM waves) for another (shock waves) to treat the skin in order to provide tissue angiogenesis in the grafted area. Such a modification involves the substitution of one known type of treatment wave for another in a process of treating skin grafts. The substitution of one known type of wave for another would have yielded predictable results to one skilled in the art at the time of the invention. However the modified George fails to teach having shock wave pulses at an energy flux density of from  $0.05\text{mJ/mm}^2$  to  $0.2\text{mJ/mm}^2$ . In the same field of endeavor Sanctis discloses a shock wave applicator applied to the skin having pulses with an energy flux density of  $0.03\text{mJ/mm}^2$  to  $0.5\text{mJ/mm}^2$  (See Abstract). It would have been obvious to have modified George to apply pulses with such a specific flux density in order to increase microcirculation. With respect to claims 37, 39, Ogden discloses applying focused shock waves (col. 3, lines 55-60). With respect to claims 40-46 and 53-56 the specific size of the area in which the shock wave is to be applied would have been obvious depending on the specific size of the wound.

4. Claims **38 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over George et al (US 6,334,069) in view of Ogden et al. (US 6,390,995) in view of Sanctis et al. "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia", as applied to claims 37, 46 above and in further view of Applicant's

admission of record. George discloses the systems and methods as disclosed above, but fails to specifically teach the shock waves include unfocused shock waves. However, in the applicant's specification is disclosed that the industry provides two main generation methods of extracorporeal shock waves focused and unfocused (see para. 0066, of applicant's specification). Therefore, having unfocused shock waves is well known expedient. It would have been obvious to have modified George to have unfocused shock waves signals in order to treat the wound with a desired shock wave.

### ***Response to Arguments***

5. Applicant's amendments to the claims are sufficient to overcome the 35 USC 112, first paragraph rejection set forth in the previous Office Action.
6. Applicant's arguments filed 11/22/2011 have been fully considered but they are not persuasive. The applicant argues that it would not have been obvious to modify the EM shock waves disclosed by the primary reference of George with the acoustic shock waves disclosed by the secondary reference of Ogden. First it should be noted that the applicant argues the use of acoustic shock waves by the invention, and although such acoustic shock waves are disclosed in the specification, the claims fail to positively set forth acoustic shock waves; they merely set forth the use of shock waves. Second, it should be noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As pointed in the rejection above, the EM shock wave disclosed by George provides healing treatment to burns and surgically implanted skin graft (see abstract, col. 10, lines 18-26). The acoustic shock waves provided by Ogden et al. induce soft tissue morphogens and growth factors (see col. 3, lines 17-44). Therefore, both shock waves induce and

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provide healing characteristics to tissue. Thus, the Examiner maintains that it would have been obvious to one skilled in the art to replace one type of wave (EM waves) for another (acoustic shock waves, as disclosed by the Ogden) to treat the skin in order to provide tissue angiogenesis in the grafted area. Such a modification involves the substitution of one known type of treatment wave for another in a process of treating skin grafts. The substitution of one known type of wave for another would have yielded predictable results to one skilled in the art at the time of the invention.

7. Regarding applicant arguments toward the prior art of record of Haput and Chvapil disclosed in the applicant specification, the applicant quote *"In contrast to the study of Haput and Chvapil, where a low number of impulses was applied, the present invention surprisingly revealed that the application of at least 200,k preferable at least 350, most preferably at least 500 impulses allows a successful treatment of soft tissue orders"*. First it should be noted that the Examiner maintains that the modified George discloses the claimed limitation. However the applicant should be aware that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH SANTOS whose telephone number is 571-270-7782. The examiner can normally be reached on Monday through Friday 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRIAN CASLER can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.S./  
Examiner, Art Unit 3737

/BRIAN CASLER/  
Supervisory Patent Examiner, Art  
Unit 3737

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